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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,586	10/22/2003	George Chin-Sheng Chou	BHT-3092-393	3865
7590 06/01/2004				
BRUCE H. TROXELL SUITE 1404 5205 LEESBURGH PIKE FALLS CHURCH, VA 22041		EXAMINER HUANG, EVELYN MEI		
		ART UNIT 1625		

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/689,586	<b>Applicant(s)</b> CHOU ET AL.	
	<b>Examiner</b> Evelyn Huang	<b>Art Unit</b> 1625	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 10-16 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

### **DETAILED ACTION**

1. Claims 10-16 are pending. Claims 1-9, 17-20 have been canceled according to the preliminary amendment filed on 10-22-2003.

#### ***Priority***

2. This application is the divisional of 10/428137. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claim 10,
  - Step (a) and step (b), the term 'mixture' is misleading since it implies that reacting the phthalimidemethyl-dimethylangelicin and hydrazine hydrate as recited does not lead to a product compound.
  - Step (c), meaning of the 'organic layer of the mixture' is unclear. Does the 'mixture' refer to the mixture of the product compound and the organic extracting solvent, or the 'mixture of phthalimidemethyl-dimethylangelicin and hydrazine hydrate'?

b. Claim 11, 'solvent' has no antecedent basis in the base claim 10.

The rejection is applicable to claims dependent on the above claims.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-14, 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, is only enabling for the process of making the hydrochloride of 4'-(aminomethyl)-4, 5'-dimethylangelicin wherein the acid gas is HCl gas as recited in claim 15. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

It is well known in the art that the hydrochloride of 4'-(aminomethyl)-4, 5'-dimethylangelicin can only form from the introduction of the HCl gas to the 4'-(aminomethyl)-4, 5'-dimethylangelicin as set forth in instant claim 15. Introduction of any other acid gas would not yield the hydrochloride of 4'-(aminomethyl)-4, 5'-dimethylangelicin as recited in the instant process. Teaching on how to make the hydrochloride 4'-(aminomethyl)-4, 5'-dimethylangelicin by introducing other acid gas is not described in the specification. Undue experimentation would therefore be required to use the process as claimed.

Amending the claims to incorporate the limitation of claim 15 would obviate this rejection.

***Conclusion***

5. Baccichetti (4312883) discloses the process of making the hydrochloride of 4'-(aminomethyl)-4, 5'-dimethylangelicin by reacting phthalimidemethyl-dimethylangelicin and hydrazine hydrate, followed by addition of HCl in solution (column 19, line 45 to column 20, line 9). Baccichetti's process requires several evaporation steps. In the instant process, HCl gas

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is introduced to the organic layer containing the 4'-(aminomethyl)-4, 5'-dimethylangelicin. The instant process has less drying steps and leads to higher yield with less solvent use and shorter working time (page 6 of the specification). The instant is therefore unobvious over the process of Baccichetti.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Evelyn Huang

Primary Examiner

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